Mr. WAXMAN. How can you as a chief executive of a company manufacturing a product that has been accused of killing so many people, not know this information? How is it?

Mr. JAMES JOHNSTON. I'm telling you that number is generated by a computer and it makes two important assumptions. The first is that virtually everyone that smokes and dies, dies because they smoke unless they got run over by a bus. And, second, that model allows people to die one, two, three, four times. I don't know how that can happen. But that is what that model does.

Mr. WAXMAN. Well, I'm struck by the overwhelming scientific agreement on the dangers of smoking. The U.S. Public Health Service, the Surgeon General, the Food and Drug Administration, the World Health Organization, The National Cancer Institute, the American Medical Association. I guess, all of these groups you would call the anti-tobacco industry. They all say it's hazardous. The experts also agree that smoking causes heart disease. Do you agree that smoking causes heart disease?

Mr. JAMES JOHNSTON. It may.

Mr. WAXMAN. OK. They agree that smoking causes lung cancer, do you agree?

Mr. JAMES JOHNSTON. It may.

Mr. WAXMAN. Do you know whether it does?

Mr. JAMES JOHNSTON. I do not know.

Mr. WAXMAN. Why not?

Mr. JAMES JOHNSTON. Because all of that is——

Mr. WAXMAN. Proprietary?

Mr. JAMES JOHNSTON [continuing]. Statistically generated data. It is epidemiological as opposed to empirical. There have been no laboratory studies which have been able to confirm any statistic——

Mr. WAXMAN. My colleague, John Bryant, said in his opening statement, his grandfather smoked all of his life and died of lung cancer. Do you think that lung cancer was caused by smoking?

Mr. JAMES JOHNSTON. I don't know, Mr. Chairman.

Mr. WAXMAN. OK. The medical experts agree that smoking causes emphysema. Do you agree?

Mr. JAMES JOHNSTON. It may.

Mr. WAXMAN. They agree that smoking causes bladder cancer, stroke, and low birth weight. Do you agree?

Mr. JAMES JOHNSTON. It may.

Mr. WAXMAN. Mr. Tisch, I want to move to you for a moment. In a deposition last year, you were asked whether cigarette smoking causes cancer. Your answer was, quote, "I don't believe so." Do you stand by that answer today?

Mr. TISCH. Yes, Sir.

Mr. WAXMAN. Do you understand how isolated you are in that belief from the entire scientific community?

Mr. TISCH. I do, Sir.

Mr. WAXMAN. You are the head of a manufacturer of a product that's been accused by the overwhelming scientific community to cause cancer, and you don't know? Do you have an interest in finding out?

Mr. TISCH. I do, Sir. Yes.

Mr. WAXMAN. And what have you done to pursue that interest?

Mr. TISCH. We have looked at the data, and the data that we have been able to see has all been statistical data that has not convinced me that smoking causes death.

Mr. WAXMAN. Mr. Campbell, you were also deposed. And you said, quote, "To my knowledge it has not been proven that cigarette smoking causes cancer." This is a rather passive and puzzling approach, especially in light of the consensus not by some but all of the scientific community. Will you ever be convinced? What evidence are you waiting for? And let's have the microphone passed over.

Mr. CAMPBELL. Yes, I may be convinced. We don't know what causes cancer, in general, right now, so I think that we may find out what causes cancer, and we may find out some relationship, which has yet to be proven.

Mr. WAXMAN. I must say, this is rather a passive approach. Don't you feel you have an obligation, the same obligation that every other consumer company has to determine whether you are causing harm, and to take steps to minimize that harm? You are not meeting that responsibility.

And it's clear your views on the health impact of cigarettes are out of step with the overwhelming scientific evidence. If all the medical people, who don't work for you, say it causes cancer, what more do you need to understand that that is the case, and accept it, and then try to work constructively to try to see if we can avoid that terrible tragedy to so many people?

Mr. CAMPBELL. Is there a question, Sir?

Mr. WAXMAN. That's the question.

Mr. CAMPBELL. I'm sorry, it was too long for me to——

Mr. WAXMAN. Well, I think the point I'm making is that all of you have some responsibility not simply to say you don't know, even when the overwhelming weight of scientific evidence is against you. I think you have an obligation to know. In my view, at the center of the entire debate over tobacco is nicotine. This ingredient in tobacco has an enormous impact on humans.

At our last hearing, Mr. Spears told the subcommittee that nicotine is an important flavor. In contrast, Dr. Kessler said the taste of nicotine is actually bitter, and can be replicated through the addition of pepper. Dr. Kessler also told the subcommittee that he was unaware of any purpose for the inclusion of nicotine in a tobacco product except for it's addictive effect. Yet Mr. Spears insisted to the subcommittee that nicotine was a flavor.

I want to cite, at this point, a document entitled, "Tobacco Flavoring for Smoking Products." The document was published by the RJ Reynolds Tobacco Company in 1972. The document lists hundreds of potential flavorings for tobacco, and rates them for smoke taste and smoke aroma. But neither nicotine nor nicotine sulphate is listed as an additive. Am I missing something, Mr. Johnston? This is RJ Reynolds. Why wasn't nicotine listed as a tobacco flavoring? Or do you disagree with Mr. Spears?

Mr. JAMES JOHNSTON. I would want to see the document, but I think I can give you the general answer to that. Nicotine is the natural component of tobacco leaf, and therefore would not be an added ingredient. Nicotine sulphate, as everyone here has testified,

is required by the Bureau of Alcohol, Tobacco, and Firearms in miniscule quantities.

Mr. WAXMAN. So you say it's not a flavor because it wasn't added?

Mr. JAMES JOHNSTON. That was a document, as I recall, that addresses flavors and aromas.

Mr. WAXMAN. So you submit then that it is not listed as a flavor in your company's document, because it's a natural ingredient in the tobacco?

Mr. JAMES JOHNSTON. I would have to look at that document, understand what it's purpose and intent is. I'm trying to give you a generalized answer to a publication 22 years old.

Mr. WAXMAN. Well, we're going to move on. We'll get back to some of these issues. Mr. Bliley?

Mr. BLILEY. Mr. Campbell, allegations have been made that the cigarette industry adds or controls nicotine to hook smokers. But it seems inconsistent with a number of facts, including Philip Morris' development of a virtually nicotine-free cigarette. Did Philip Morris spend about $200 million in the late 1980's building a plant capable of producing denicotinized tobacco in commercial quantities?

Mr. CAMPBELL. On expenses and in promoting and trying to sell the product, yes, sir.

Mr. BLILEY. It Philip Morris a long time to develop a denicotinized cigarette, isn't that because the technology for selectively removing nicotine from tobacco was unavailable until recently?

Mr. CAMPBELL. It was very unusual technology. When we acquired the Maxwell House Company, we saw their decaffeination process over in Europe. And it's a very selective type of process, and we were able to take out the nicotine without taking out a lot of other things, so we applied that technology, yes, sir.

Mr. BLILEY. Am I correct that between 1986 and 1989 Philip Morris research and development team, working with a marketing team, tested different blends using denicotinized tobacco in an attempt to produce a cigarette with all the other desirable properties of cigarettes, but no nicotine?

Mr. CAMPBELL. Innumerable man hours, sir. That work actually still continues today.

Mr. BLILEY. My understanding is that Philip Morris denicotized cigarettes failed in marketplace because consumers didn't like the way they tasted, is that correct?

Mr. CAMPBELL. That's exactly correct. People found them a little bit lacking in taste and flavor. And the other word they used was "flat," which relates to, I guess, mouth impact. Nicotine seems to have an impact that's like carbonation in a soda.

Mr. BLILEY. Mr. Johnston, didn't you have a similar experience with your so-called, well, your tobacco-free cigarette, Premier?

Mr. JAMES JOHNSTON. We were not able to provide the level of taste that smokers expected. We continue to do a lot of——

Mr. BLILEY. I know my wife is a smoker. I took a pack of your cigarettes, those, home and she took three puffs, put it down never to pick it up again. She said it tasted terrible.

Mr. JAMES JOHNSTON. Sometimes the greatest attempts at technology fail to provide consumers with what they want, despite whatever advantages that product might bring.

Mr. BLILEY. Mr. Campbell, aside from taste, wasn't the initial failure of Next also attributable to the fact that there were already a number of brands on the market with virtually no nicotine, and consumers therefore did not perceive the even greater reduction of nicotine in Next as a selling point?

Mr. CAMPBELL. That's correct. There is some major brands that have under one milligram of tar and under 0.1 milligrams of nicotine, so that made the competitive marketplace difficult.

Mr. BLILEY. Do you think the marketing of Next was hindered by petitions from the Coalition on Smoking OR Health which argued that the elimination of nicotine from the product made it a drug under the food and drug laws?

Mr. CAMPBELL. Yes. And I think Mr. Johnston pointed out the irony of that in his prepared remarks.

Mr. BLILEY. Did members of the Coalition on Smoking OR Health ironically argue to the FDA that Philip Morris' denicotized Next cigarettes posed a greater health hazard to smokers than ordinary cigarettes?

Mr. CAMPBELL. That's exactly correct, sir.

Mr. BLILEY. Isn't that petition position totally contrary to what they and Dr. Kessler are now saying, which is that products without nicotine should be the only ones allowed in the marketplace?

Mr. CAMPBELL. Yes. I think, as many of my colleagues said, there is great ironies here. We do something and we get—for it, and we do something and we do something else and we get—for that as well. So, it's difficult for us, sir.

Mr. BLILEY. What was Philip Morris' objective in marketing it's denicotized Next cigarettes?

Mr. CAMPBELL. Our objective was to try to get a piece of the marketplace, because we try to provide what the public wants.

Mr. BLILEY. When you say, "a piece of the marketplace," you know, I've heard different figures, but 1 percent in the marketplace, of all sales of cigarettes, what does that mean in dollars?

Mr. CAMPBELL. Oh, I guess, about $150 million, sir.

Mr. BLILEY. So that's a reason to be very competitive, I would think.

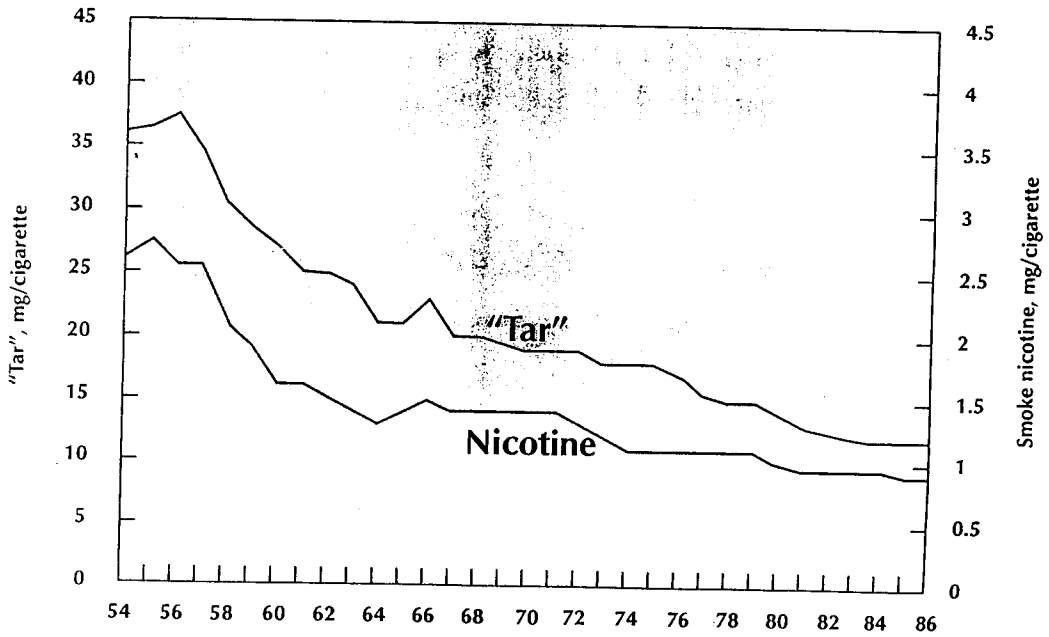
Mr. CAMPBELL. I think it is, yes, sir.

Mr. BLILEY. Mr. Johnston, at last week's hearing, data was presented from the Surgeon General's Report which showed a dramatic reduction in tar and nicotine levels over 30 years. Dr. Kessler, during his testimony, showed us several graphs which showed us dramatically different results. His graphs showed nicotine increasing, and tar decreasing over the period 1982-1991.

First, let's examine the first graph, which is taken from the 1989 Surgeon General's Report. This graph documents the decline of tar and nicotine from the 1950's to the 1990's. For both tar and nicotine there has been a 69 percent reduction.

[The graphs referred to follow:]

1954-1986
Sales-Weighted Average "Tar" and Nicotine Yields



Source: U.S. Surgeon General Report

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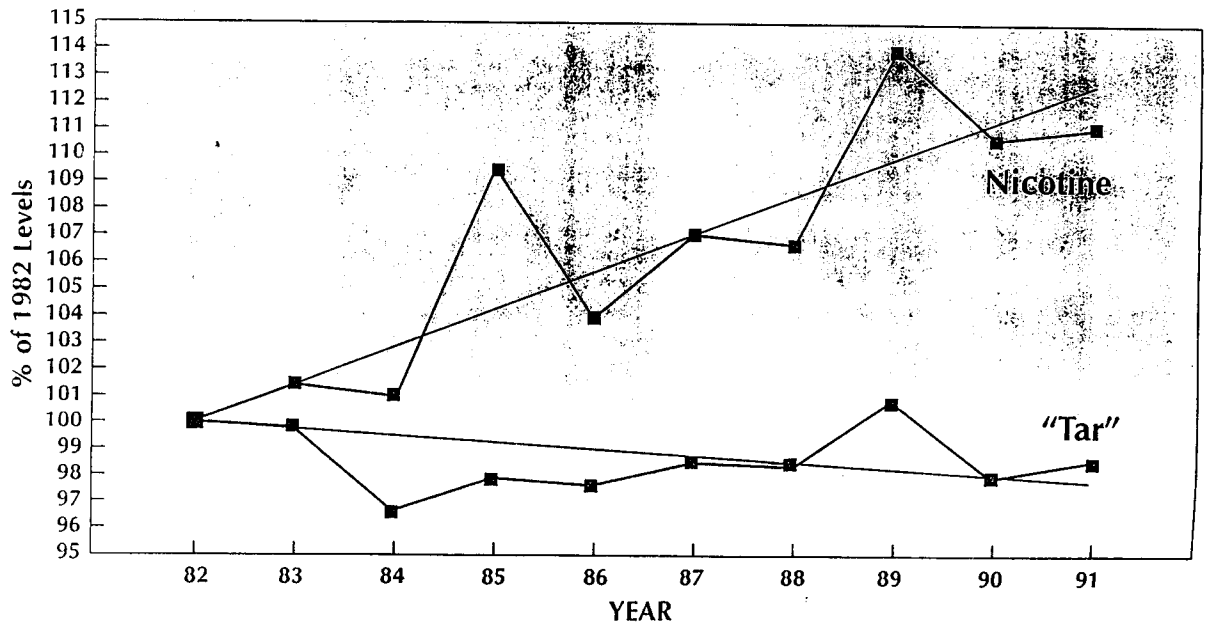
Sales-Weighted Nicotine and "Tar" Levels in Smoke

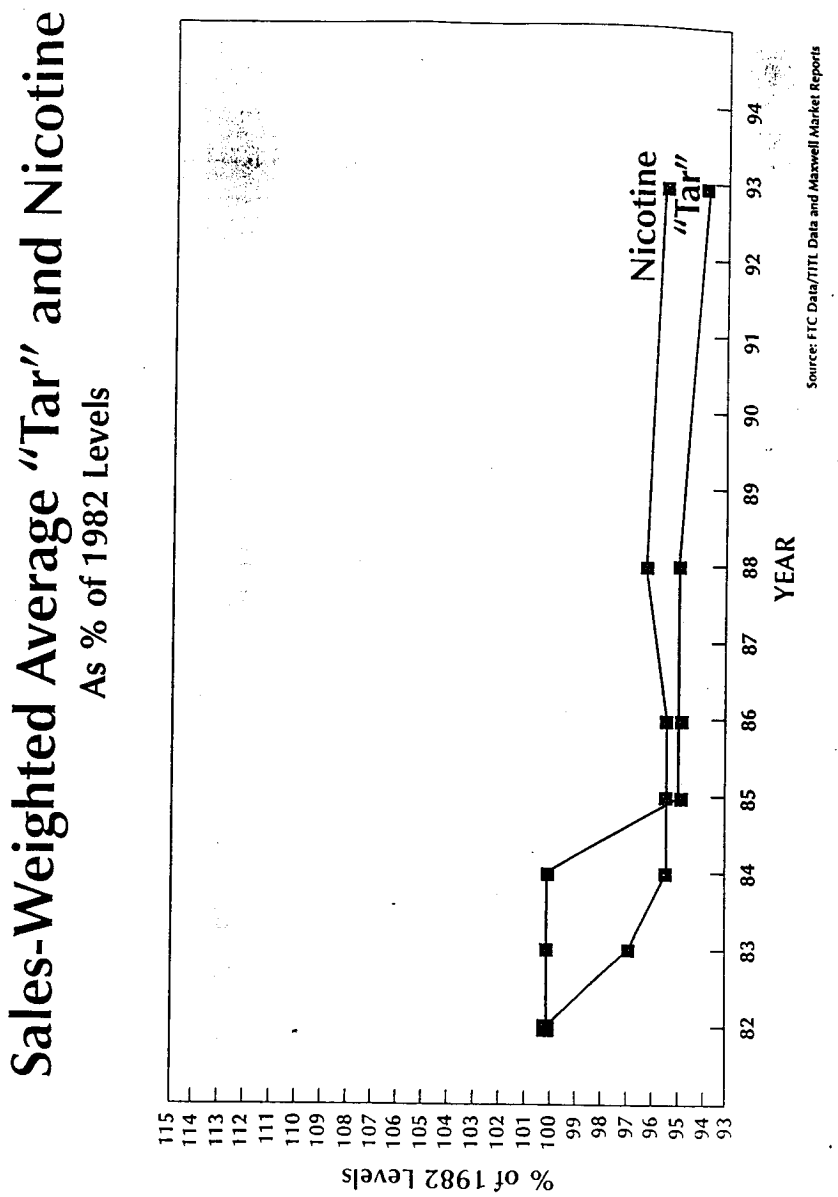
As % of 1982 Levels

(Average of All Brands)



Source: "Kessler"

625



Mr. BLILEY. This graph shows that nicotine levels are a function of tar levels in tobacco. When tar levels are set, nicotine levels follow. And as the manufacturers have reduced their tar levels over the years, nicotine levels have correspondingly fallen.

Now, the second chart, which is taken from Dr. Kessler's testimony shows the opposite. His chart shows that as tar levels have fallen, nicotine has actually risen. I understand that your company has run a further analysis of this data. Could you please explain the differences in these graphs?

Mr. JAMES JOHNSTON. Yes, Congressman, I can. First, going back to the Surgeon General's data, which were presented at the previous hearing, we went back—the Surgeon General's data, David, please?

Just to make sure that those data were correct, we went back and selectively recalculated data. Our data were exactly in line with the Surgeon General's data which show a steady and quite remarkable decline in tar and nicotine deliveries. Certainly not an indication of increasing nicotine or addiction, or any of that sort of thing, with a 65 percent reduction in nicotine, a 67 percent reduction in tar, based on what people are actually smoking in the United States.

The FDA chart was quite startling and amazing to us, and so we set about immediately to try to reconstruct those data. We contacted the FDA and asked them to share their data with us. We believe the FDA calculations are incorrect. They used several simplifying assumptions, and took just the three basic categories, made three multiplications, full flavor times average tar and nicotine, low tar, and ultra low tar.

We went back and calculated for that 10 year period every single one of the 500 brand styles times their exact tar and nicotine number, times their exact sales in the marketplace. So, if you'll show chart three? This is precisely what Americans smoked on average for that 10 year period. And what you see, and what we expected to see, and what we have now confirmed, is that both tar and nicotine levels did decline during that period.

You do get changes year to year because we are dealing with an agricultural crop, based on sunlight, and rain, and wind, and all those sorts of things. Nicotine naturally varies year to year, so you get little changes. I want to be very clear Congressman. I am not accusing Dr. Kessler of manipulating data. I know how it is to be falsely accused. We have contacted the FDA. We are providing them with our calculations, and we have offered to be any help we can.

But it was Dr. Kessler's chart that was picked up by every newspaper in this country, and on television, as the proof that we were manipulating nicotine, and it was wrong.

Mr. BLILEY. When you say, Mr. Johnston, that sunlight, moisture vary the amount of nicotine in a stalk of tobacco, what kind of variance do you get from, say, a very dry summer, a hot summer, to a relatively cool summer, and a wet summer?

Mr. JAMES JOHNSTON. Mr. Congressman. You have just gone beyond my technical ability to answer that question. Mr. Schindler?

Mr. SCHINDLER. I don't know the exact numbers, but my understanding is that the ratio of nicotine to weight in the leaf varies

according to the rainfall in the growing season. The amount of nicotine in a leaf is essentially the same regardless of the size and weight of the leaf. In a dry season, the leaf is smaller so it has more nicotine relative to the smaller size and weight of the leaf. In a wet season, the leaf is larger so it has less nicotine relative to the larger size and weight of the leaf.

Mr. WAXMAN. Thank you, Mr. Bliley, we'll have to get that statement reiterated for the record. I don't know if it was picked up. You'll see later if it was on the record.

Mr. Wyden?

Mr. WYDEN. Thank you, Mr. Chairman. Just before we go to the subject of my questioning, I know that the witnesses want to turn this to the battle of the charts, I guess, with respect to Dr. Kessler and the FDA. We're going to get into it later, but we believe that the chart in question, with respect to the FDA, is an accurate one, and we'll get into it a little bit later.

Let me begin my questioning on the matter of whether or not nicotine is addictive. Let me ask you first, and I'd like to just go down the row, whether each of you believes that nicotine is not addictive. I heard virtually all of you touch on it. Yes or no, do you believe nicotine is not addictive?

Mr. CAMPBELL. I believe nicotine is not addictive, yes.

Mr. WYDEN. Mr. Johnston?

Mr. JAMES JOHNSTON. Mr. Congressman, cigarettes and nicotine clearly do not meet the classic definition of addiction. There is no intoxication.

Mr. WYDEN. We'll take that as a "no." Again, time is short. I think each of you believe that nicotine is not addictive. We would just like to have this for the record.

Mr. TADDEO. I don't believe that nicotine or our products are addictive.

Mr. TISCH. I believe that nicotine is not addictive.

Mr. HORRIGAN. I believe that nicotine is not addictive.

Mr. SANDEFUR. I believe that nicotine is not addictive.

Mr. DONALD JOHNSTON. And I, too, believe that nicotine is not addictive.

Mr. WYDEN. Dr. Campbell, I assume that you are aware that your testimony, and you said in your testimony that nicotine is not addictive is contradicted by an overwhelming number of authorities and associations. For example, in 1988, the Surgeon General of the United States wrote an entire report on this topic. The Surgeon General, of course, is the chief health advisor to our government. I assume that you have reviewed that report?

Mr. CAMPBELL. Yes, I have, Sir.

Mr. WYDEN. All right. Exhibit 1 excerpts from the report. And I'm going to ask the clerk from our committee to give you an exhibit. And I would ask unanimous consent, Mr. Chairman, to put this exhibit into the record as well?

Mr. WAXMAN. Without objection, that will be the order.

[Testimony resumes on p. 640.]

[Exhibit No. 1 follows:]

— Exhibit 1

THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION

(A Report of the Surgeon General)

FOREWORD

This 20th Report of the Surgeon General on the health consequences of tobacco use provides an additional important piece of evidence concerning the serious health risks associated with using tobacco.

The subject of this Report, nicotine addiction, was first mentioned in the 1964 Report of the Advisory Committee to the Surgeon General, which referred to tobacco use as "habituating." In the landmark 1979 Report of the Surgeon General, by which time considerably more research had been conducted, smoking was called "the prototypical substance-abuse dependency." Scientists in the field of drug addiction now agree that nicotine, the principal pharmacologic agent that is common to all forms of tobacco, is a powerfully addicting drug.

Recognizing tobacco use as an addiction is critical both for treating the tobacco user and for understanding why people continue to use tobacco despite the known health risks. Nicotine is a psychoactive drug with actions that reinforce the use of tobacco. Efforts to reduce tobacco use in our society must address all the major influences that encourage continued use, including social, psychological, and pharmacologic factors.

After carefully examining the available evidence, this Report concludes that:

- Cigarettes and other forms of tobacco are addicting.
- Nicotine is the drug in tobacco that causes addiction.
- The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

We must recognize both the potential for behavioral and pharmacologic treatment of the addicted tobacco user and the problems of withdrawal. Tobacco use is a disorder which can be remedied through medical attention; therefore, it should be approached by health care providers just as other substance-use disorders are approached: with knowledge, understanding, and persistence. Each health care provider should use every available clinical opportunity to encourage or assist smokers to quit and to help former smokers to maintain abstinence.

To maintain momentum toward a smoke-free society, we also must take steps to prevent young people from beginning to smoke. First, we must insure that every child in every school in this country is educated as to the health risks and the addictive nature of tobacco use. Most jurisdictions require that school curricula include prevention of drug use; therefore, education on the prevention of tobacco use should be included in this effort. Second, warning labels regarding the addictive nature of tobacco use should be required for all tobacco packages and advertisements. Young people in particular may not be aware of the risk of tobacco addiction. Finally, parents and other role models should discourage smoking and other forms of tobacco use among young people. Parents who quit set an example for their children.

Smoking continues to be the chief preventable cause of premature death in this country. Nicotine has addictive properties which help to sustain widespread tobacco use. It is gratifying to see the decline in reported smoking prevalence and cigarette consumption in the United States during the past 25 years. However, we cannot expect to see a sustained decline in rates of smoking-related cancers, cardiovascular disease, and pulmonary disease without sustained public health efforts against tobacco use.

The Public Health Service is committed to preventing tobacco use among youth and to promoting cessation among existing smokers. We hope that this Report will assist the health care community, voluntary health agencies, and our Nation's schools in working with us to reduce tobacco use in our society.

Robert E. Windom, M.D.
Assistant Secretary for Health

PREFACE

This Report of the Surgeon General is the U.S. Public Health Service's 20th Report on the health consequences of tobacco use and the 7th issued during my tenure as Surgeon General. Eighteen Reports have been released previously as part of the health consequences of smoking series; a report on the health consequences of using smokeless tobacco was released in 1986.

Previous Reports have reviewed the medical and scientific evidence establishing the health effects of cigarette smoking and other forms of tobacco use. Tens of thousands of studies have documented that smoking causes lung cancer, other cancers, chronic obstructive lung disease, heart disease, complications of pregnancy, and several other adverse health effects.

Epidemiologic studies have shown that cigarette smoking is responsible for more than 300,000 deaths each year in the United States. As I stated in the Preface to the 1982 Surgeon General's Report, smoking is the chief avoidable cause of death in our society.

From 1964 through 1979, each Surgeon General's Report addressed the major health effects of smoking. The 1979 Report provided the most comprehensive review of these effects. Following the 1979 Report, each subsequent Report has focused on specific populations (women in 1980, workers in 1985), specific diseases (cancer in 1982, cardiovascular disease in 1983, chronic obstructive lung disease in 1984), and specific topics (low-tar, low-nicotine cigarettes in 1981, involuntary smoking in 1986).

This Report explores in great detail another specific topic: nicotine addiction. Careful examination of the data makes it clear that cigarettes and other forms of tobacco are addicting. An extensive body of research has shown that nicotine is the drug in tobacco that causes addiction. Moreover, the processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

Actions of Nicotine

All tobacco products contain substantial amounts of nicotine. Nicotine is absorbed readily from tobacco smoke in the lungs and from smokeless tobacco in the mouth or nose. Levels of nicotine in

the blood are similar in magnitude in people using different forms of tobacco. Once in the blood stream, nicotine is rapidly distributed throughout the body.

Nicotine is a powerful pharmacologic agent that acts in a variety of ways at different sites in the body. After reaching the blood stream, nicotine enters the brain, interacts with specific receptors in brain tissue, and initiates metabolic and electrical activity in the brain. In addition, nicotine causes skeletal muscle relaxation and has cardiovascular and endocrine (i.e., hormonal) effects.

Human and animal studies have shown that nicotine is the agent in tobacco that leads to addiction. The diversity and strength of its actions on the body are consistent with its role in causing addiction.

Tobacco Use as an Addiction

Standard definitions of drug addiction have been adopted by various organizations including the World Health Organization and the American Psychiatric Association. Although these definitions are not identical, they have in common several criteria for establishing a drug as addicting.

The central element among all forms of drug addiction is that the user's behavior is largely controlled by a psychoactive substance (i.e., a substance that produces transient alterations in mood that are primarily mediated by effects in the brain). There is often compulsive use of the drug despite damage to the individual or to society, and drug-seeking behavior can take precedence over other important priorities. The drug is "reinforcing"—that is, the pharmacologic activity of the drug is sufficiently rewarding to maintain self-administration. "Tolerance" is another aspect of drug addiction whereby a given dose of a drug produces less effect or increasing doses are required to achieve a specified intensity of response. Physical dependence on the drug can also occur, and is characterized by a withdrawal syndrome that usually accompanies drug abstinence. After cessation of drug use, there is a strong tendency to relapse.

This Report demonstrates in detail that tobacco use and nicotine in particular meet all these criteria. The evidence for these findings is derived from animal studies as well as human observations. Leading national and international organizations, including the World Health Organization and the American Psychiatric Association, have recognized chronic tobacco use as a drug addiction.

Some people may have difficulty in accepting the notion that tobacco is addicting because it is a legal product. The word "addiction" is strongly associated with illegal drugs such as cocaine and heroin. However, as this Report shows, the processes that

determine tobacco addiction are similar to those that determine addiction to other drugs, including illegal drugs.

In addition, some smokers may not believe that tobacco is addicting because of a reluctance to admit that one's behavior is largely controlled by a drug. On the other hand, most smokers admit that they would like to quit but have been unable to do so. Smokers who have repeatedly failed in their attempts to quit probably realize that smoking is more than just a simple habit.

Many smokers have quit on their own ("spontaneous remission") and some smokers smoke only occasionally. However, spontaneous remission and occasional use also occur with the illicit drugs of addiction, and in no way disqualify a drug from being classified as addicting. Most narcotics users, for example, never progress beyond occasional use, and of those who do, approximately 30 percent spontaneously remit. Moreover, it seems plausible that spontaneous remitters are largely those who have either learned to deliver effective treatments to themselves or for whom environmental circumstances have fortuitously changed in such a way as to support drug cessation and abstinence.

Treatment

Like other addictions, tobacco use can be effectively treated. A wide variety of behavioral interventions have been used for many years, including aversion procedures (e.g., satiation, rapid smoking), relaxation training, coping skills training, stimulus control, and nicotine fading. In recognition of the important role that nicotine plays in maintaining tobacco use, nicotine replacement therapy is now available. Nicotine polacrilex gum has been shown in controlled trials to relieve withdrawal symptoms. In addition, some (but not all) studies have shown that nicotine gum, as an adjunct to behavioral interventions, increases smoking abstinence rates. In recent years, multicomponent interventions have been applied successfully to the treatment of tobacco addiction.

Public Health Strategies

The conclusion that cigarettes and other forms of tobacco are addicting has important implications for health professionals, educators, and policy-makers. In treating the tobacco user, health professionals must address the tenacious hold that nicotine has on the body. More effective interventions must be developed to counteract both the psychological and pharmacologic addictions that accompany tobacco use. More research is needed to evaluate how best to treat those with the strongest dependence on the drug. Treatment of tobacco addiction should be more widely available and should be

considered at least as favorably by third-party payors as treatment of alcoholism and illicit drug addiction.

The challenge to health professionals is complicated by the array of new nicotine delivery systems that are being developed and introduced in the marketplace. Some of these products are produced by tobacco manufacturers; others may be marketed as devices to aid in smoking cessation. These new products may be more toxic and more addicting than the products currently on the market. New nicotine delivery systems should be evaluated for their toxic and addictive effects; products intended for use in smoking cessation also should be evaluated for efficacy.

Public information campaigns should be developed to increase community awareness of the addictive nature of tobacco use. A health warning on addiction should be rotated with the other warnings now required on cigarette and smokeless tobacco packages and advertisements. Prevention of tobacco use should be included along with prevention of illicit drug use in comprehensive school health education curricula. Many children and adolescents who are experimenting with cigarettes and other forms of tobacco state that they do not intend to use tobacco in later years. They are unaware of, or underestimate, the strength of tobacco addiction. Because this addiction almost always begins during childhood or adolescence, children need to be warned as early as possible, and repeatedly warned through their teenage years, about the dangers of exposing themselves to nicotine.

This Report shows conclusively that cigarettes and other forms of tobacco are addicting in the same sense as are drugs such as heroin and cocaine. Most adults view illegal drugs with scorn and express disapproval (if not outrage) at their sale and use. This Nation has mobilized enormous resources to wage a war on drugs — illicit drugs. We should also give priority to the one addiction that is killing more than 300,000 Americans each year.

We as citizens, in concert with our elected officials, civic leaders, and public health officers, should establish appropriate public policies for how tobacco products are sold and distributed in our society. With the evidence that tobacco is addicting, is it appropriate for tobacco products to be sold through vending machines, which are easily accessible to children? Is it appropriate for free samples of tobacco products to be sent through the mail or distributed on public property, where verification of age is difficult if not impossible? Should the sale of tobacco be treated less seriously than the sale of alcoholic beverages, for which a specific license is required (and revoked for repeated sales to minors)?

In the face of overwhelming evidence that tobacco is addicting, policy-makers should address these questions without delay. To achieve our goal of a smoke-free society, we must give this problem the serious attention it deserves.

C. Everett Koop, M.D., Sc.D.
Surgeon General

Chapter II: Nicotine: Pharmacokinetics, Metabolism, and Pharmacodynamics

1. All tobacco products contain substantial amounts of nicotine and other alkaloids. Tobaccos from low-yield and high-yield cigarettes contain similar amounts of nicotine.
2. Nicotine is absorbed readily from tobacco smoke in the lungs and from smokeless tobacco in the mouth or nose. Levels of nicotine in the blood are similar in magnitude in people using different forms of tobacco. With regular use, levels of nicotine accumulate in the body during the day and persist overnight. Thus, daily tobacco users are exposed to the effects of nicotine for 24 hr each day.
3. Nicotine that enters the blood is rapidly distributed to the brain. As a result, effects of nicotine on the central nervous system occur rapidly after a puff of cigarette smoke or after absorption of nicotine from other routes of administration.
4. Acute and chronic tolerance develops to many effects of nicotine. Such tolerance is consistent with reports that initial

Mr. WYDEN. We'll wait just a moment, Dr. Campbell, so that you can have the exhibit.

All right. At page 4, you'll note that the Surgeon General lays out the standard definition of drug addiction that's been adopted by various organizations, including the World Health Organization and the American Psychiatric Association.

Here is what the Surgeon General said, with respect to the elements, on drug addiction. First, the central element among all forms of drug addiction is that the behavior of the user is largely controlled by a psychoactive substance. Second, there is often compulsive use of the drug despite damage to the individual or to society. And drug-seeking behavior can take precedence over other important priorities.

Third, the drug is reinforcing. That is, it is the pharmacologic of the drug is sufficiently rewarding to maintain self-administration. Fourth, tolerance is another aspect of drug addiction, whereby a given dose of the drug produces less effect, or increasing doses are required to achieve a specified intensity of response.

Fifth, the physical dependence on the drug can also occur, and is characterized by withdrawal syndrome that usually accompanies drug abstinence. Six, after cessation of drug use, there is a strong tendency to relapse.

Now, the Surgeon General goes on to state, and I quote, "This report demonstrates in detail that tobacco use and nicotine, in particular, meet all these criteria."

Do you still disagree with the conclusion of the Surgeon General?

Mr. CAMPBELL. I have a common sense definition of addiction which tells me that, first of all, I'm a smoker and I'm not a drug addict. And, basically, I can function in quite a normal way, my judgment is not impaired, I like most smokers don't have an indication of—there is no indication that there is tolerance at play here. People smoke the same amount——

Mr. WYDEN. We'll say you disagree because time is short.

Mr. CAMPBELL. OK, fine. Thank you.

Mr. WYDEN. In Chapter 4, the Surgeon General reaches the following conclusions. They appear on page 14 of this same exhibit. First, cigarettes and other forms of tobacco are addicting, patterns of tobacco use are regular and compulsive, and a withdrawal syndrome usually accompanies tobacco abstinence. Are you familiar with this statement by the Surgeon General?

Mr. CAMPBELL. I'm just catching up to you, sir. I'm sorry Congressman Wyden. Would you——

Mr. WYDEN. Do you disagree with that statement from the Surgeon General?

Mr. CAMPBELL. I think that it is rather ironic that the Surgeon General in 1964 did not conclude that cigarettes were addictive, and then in 1988 he seems to have changed his mind. I stick by my common sense definition. I really, you know, I think that these kind of comparisons with heroine, and cocaine, and hard drugs, are really not applicable.

Mr. WYDEN. Hopefully, we'll get a yes or no answer to some of these questions.

Mr. CAMPBELL. OK.

Mr. WYDEN. And I'd like to stick to that. Now, the Surgeon General goes on to state that nicotine is the drug in tobacco that causes addiction. Specifically, nicotine is psychoactive, mood altering, and can provide pleasurable effects. Nicotine can serve as a reinforcer to motivate tobacco-seeking and tobacco-using behavior. Tolerance develops such that repeat use results in diminished effect and be accompanied by increased intake. Nicotine also causes physical dependence, characterized by withdrawal syndrome that usually accompanies nicotine abstinence. Do you disagree with this statement?

Mr. CAMPBELL. Yes, I do.

Mr. WYDEN. In Chapter 5, the Surgeon General concludes, and I quote, "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroine and cocaine." Am I correct that you disagree with this statement as well?

Mr. CAMPBELL. Yes, I do. And I particularly—I think there is some people, including some anti-tobacco people that disagree with that, the characterization like heroine and cocaine.

Mr. WYDEN. Now, Dr. Campbell, the Surgeon General——

Mr. CAMPBELL. I'm not a doctor, sir, I'm sorry.

Mr. WYDEN. All right. Mr. Campbell, the Surgeon General is not exactly out there by himself with respect to the scientific community. Let me now give you Exhibit 2.

[Exhibits 2 and 3 follow:]

presence of other smokers and the widespread availability of cigarettes. When efforts to give up smoking are made, Nicotine Withdrawal may develop.

Impairment. Since nicotine, unlike alcohol, rarely causes any clinically significant state of intoxication, there is no impairment in social or occupational functioning as an immediate and direct consequence of its use.

Complications. The most common complications are bronchitis, emphysema, coronary artery disease, peripheral vascular disease, and a variety of cancers.

Prevalence and sex ratio. A large proportion of the adult population of the United States has Nicotine Dependence, the prevalence among males being greater than that among females. Among teen-age smokers, males are affected approximately as often as females.

Familial pattern. Cigarette smoking among first-degree biologic relatives of people with Nicotine Dependence is more common than among the general population. Evidence for a genetic factor has been documented, but the effect is modest.

304.00 Opioid Dependence
305.50 Opioid Abuse

See Opioid-induced Organic Mental Disorders (p. 151) for a description of Opioid Intoxication and Withdrawal.

This group includes natural opioids, such as heroin and morphine, and synthetics with morphinelike action, which act on opiate receptors. These compounds are prescribed as analgesics, anesthetics, or cough-suppressants. They include codeine, hydromorphone, meperidine, methadone, oxycodone, and others. Several other compounds that have both direct opiatelike agonist effects and antagonist effects are included in this class of substances because they often produce the same physiologic and behavioral effects as pure opioids, e.g., pentazocine and buprenorphine. Prescription opiates are typically taken orally in pill form, but can also be taken intravenously; heroin is typically taken intravenously, but can also be taken by nasal inhalation or smoking. Regular use of these substances leads to remarkably high levels of tolerance.

Although methadone is included in this class, people properly supervised in a methadone maintenance program should not develop any of the Opioid-induced Organic Mental Disorders. When the criteria for one of these diagnoses are met, this indicates that there has been nonmedical use of methadone, in which case the appropriate diagnosis should be made.

Patterns of use. There are two patterns of development of dependence and abuse. In one, which is relatively infrequent, the person originally obtained an opioid by prescription, from a physician, for the treatment of pain or cough-suppression, but has gradually increased the dose and frequency of use on his or her own. The person continues to justify the substance use on the basis of treatment of symptoms, but substance-seeking behavior becomes prominent, and the person may go to several physicians in order to obtain sufficient supplies of the substance.

A second pattern that leads to dependence or abuse involves young people in their teens or early 20s who, with a group of peers, use opioids obtained from illegal sources. Some use an opioid alone to obtain a "high," or euphoria. Others use these substances in combination with amphetamines, cannabis, hallucinogens, or sedatives to enhance the euphoria or to counteract the depressant effect of the opioid. In this

Mr. WYDEN. It is a statement from the American Psychological Association presented to this subcommittee in 1988. Now, the American Psychological Association is, of course, a professional association of psychologist, and it's got 70,000 members. And they agree with the Surgeon General's conclusion, one, that cigarette and other forms of tobacco are addicting, nicotine is the drug in tobacco that causes addiction, and it is the pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs, again, such as heroine and cocaine.

Are we correct in assuming that you disagree also with the American Psychological Association?

Mr. CAMPBELL. Yes, I do. And a lot of other people do as well.

Mr. WYDEN. Now, we have a third group, the American Psychiatric Association. And they have described, also, the addictive properties of nicotine. The American Psychiatric Association has 39,000 members. I'd like to give you now Exhibit 3, it's called the Diagnostic and Statistic Manual of Mental Disorders.

They recognize dependence as a psychoactive substance abuse disorder. I'll let the staff give you this.

I quote here. "People with this disorder are often distressed because of their inability to stop nicotine use, particularly when they have serious physical symptoms. In many cases they may experience a period of nicotine withdrawal lasting from days to weeks. The relapse rate is greater than 50 percent in the first 6 months, and at least 70 percent in the first 12 months."

The American Psychiatric Association goes on to state, nicotine withdrawal is, quote, "an organic mental syndrome and disorder." This disorder includes craving for nicotine, irritability, frustration or anger, difficulty concentrating, restlessness, decreased heart rate, increased appetite or weight gain.

Are we, again, correct in saying that you disagree with the American Psychiatric Association?

Mr. CAMPBELL. I do. And, again, many of these symptoms that are being described here are not accurate. And, you know, I stand beside the fact that 90 percent of the 40 million smokers who have quit have quit without any assistance.

Mr. WYDEN. Let's just keep building this mountain of evidence, if we could, from these medical experts because I'd like to refer you to Exhibit 4 where the American Medical Association, has also taken a position on the issue. They have 270,000 members who are doctors. I assume that you are aware that the AMA has identified nicotine as a drug of addiction. Do you disagree with the American Medical Association as well?

Mr. CAMPBELL. I don't have the documents, but I do not believe that cigarette smoking is addictive.

Mr. WYDEN. All right. The World Health Organization, a fifth organization, has taken the position that nicotine is addictive. Just so we get you this exhibit, they are, of course, the premier international public health organization.

[Exhibits 4 and 5 follow:]

Mr. WYDEN. They have stated that nicotine administration can lead to tolerance and physiological dependence. The withdrawal syndrome includes a craving for nicotine, impaired ability to concentrate, disruptive cognitive performance, mood changes, impaired brain function. Am I correct in saying that you disagree with this organization as well?

Mr. CAMPBELL. Yes, that's correct. And would you like to hear some scientific opinion on this from my standpoint as well, or not?

Mr. WYDEN. Why don't—if you could state it briefly, that'd be fine. You know, to me, the evidence, from the medical experts is overwhelming. It is unanimous. And what we will have seen in the course of the hearing that we even see the results of suppressed industry research that demonstrates addiction.

And I'm really struck by the fact that if you just go ask your customers, you'll find that this is addictive. Again, and again, I hear from smokers at home saying that they just cannot stop.

And yet in spite of this enormous amount of evidence that nicotine is addictive, in spite of the fact that all of these recognized medical leaders in a unanimous fashion say that nicotine is addictive, you all come before us and say, no.

So I would be happy to hear any arguments you have that support your point of view?

Mr. CAMPBELL. Would you like to hear from my scientist, sir?

Mr. WYDEN. Mr. Chairman? That would be fine by me?

Mr. CAMPBELL. Dr. Ellis, would you comment on the definitions of addiction?

Ms. ELLIS. Yes, Mr. Wyden. I think at issue here is a scientific definition of addiction. I do not believe that there is a consensus in the scientific community on the criteria necessary to classify a substance as additive. And, in fact, the lay community freely associates the word "addictive" to food substances such as chocolate and exercise. Therefore, it is a very complicated question which requires an extremely complicated answer.

The psychologists are not pharmacologists, nor are the medical community pharmacologists. The strict pharmacological definition of addiction involves three different criteria. They are, intoxication, physical dependence, and tolerance. And to my knowledge there is no evidence that nicotine or cigarette smoking plays in any of these definitions.

Mr. WYDEN. Tell me, if you would, because we have thousands of medical experts coming to us and saying nicotine is addicting. Certainly the Surgeon General, with a full report on the subject has spoken to it. What are your qualifications, and who pays your salary?

Dr. ELLIS. Mr. Wyden, I have a Ph.D. in pharmacology, and I'm the director of research for Philip Morris U.S.A.

Mr. WAXMAN. Would the gentleman yield to me?

Mr. WYDEN. I'd be happy to yield.

Mr. WAXMAN. I find it amazing when you have the scientific community, and we're not talking about just some people involved in this issue, we have the Surgeon General of the United States, the American Medical Association, the American Psychological Association, the American Psychiatric Association, the World Health Organization, all coming to the conclusion as they look at the issue of

addiction, that cigarette smoking is addictive. That is all on one side and on the other side are the tobacco companies. I say this because it really raises a question of credibility. Who else is on your side?

Mr. SANDEFUR. Mr. Chairman——

Mr. WAXMAN. I asked the question of this lady here.

Ms. ELLIS. Mr. Waxman, I think there is technical, scientific literature available. And some of that I know you are aware of, because it was submitted to you, that indicates that nicotine cigarette smoking does not meet these criteria.

Mr. WAXMAN. Are there any major health organizations that would agree with you?

Ms. ELLIS. We would be happy to supply that information to you, and other information that is in the scientific literature.

Mr. WAXMAN. We'll hold the record open. I thank the gentleman for yielding to me.

[The following letters were submitted:]

Mr. WYDEN. Well, Mr. Chairman, I think what is really striking is that the people who have no vested financial interest in this particular subject say that nicotine is addictive. And the people who have a vested financial interest in saying otherwise argue that it's not. Now, I could keep going on.

I note that the National Institute on Drug Abuse has said that nicotine is as addictive as heroine. They have indicated that it is like 5 to 10 times more potent than cocaine or morphine, in terms of producing effects on mood and behavior.

I have found it very interesting in listening to the testimony that we have heard already today, all of you are comparing cigarettes to traffic accidents, and television, and coffee, and soft drinks.

I don't know anybody who charged that cigarette are causing traffic accidents. I don't know anybody that's proved that coffee has caused cancer. But what we do know is that the preponderance of medical experts in our country say that nicotine is addicting, and that there is solid indisputable proof that smoking causes lung cancer.

I'm just struck by how, when the chairman and other experts pile up this mountain of evidence, report after report, the Surgeon General, the American Medical Association, the World Health Organization, report after report, after report, after report, your companies, who have a vested financial interest in saying otherwise, are the only folks who make the contention, that is contradicted even by your customers, that smoking is not addictive.

Mr. WAXMAN. Mr. Wyden, if you will yield to me. I just also want to remark on the fact that this woman is the director of research for Philip Morris, and this is a fundamental question, I would think, for the tobacco industry, whether their product is addictive, but you have reached the conclusion it isn't.

You will have to do research to find out if there is any other reputable organization, but you would think that if there were, you would know it. But we will keep the record open. And we specifically want you to submit to us your research data that indicates that this is not addicting.

Mr. CAMPBELL. Could I enter a quote, sir, on the topic of addiction?

Mr. WAXMAN. Yes, Mr. Campbell?

Mr. CAMPBELL. Could I enter a quote, Mr. Chairman, from an eminent person, with respect to addiction?

Mr. WAXMAN. Before we do that, I would like for you to submit your research data to us on this addiction question.

Mr. CAMPBELL. We said that we would submit data on addiction experts that agree with Dr. Ellis' position.

Mr. WAXMAN. But I think we should have for the record your research data showing it's not addictive.

Mr. CAMPBELL. I'm—we have——

Mr. WAXMAN. Let me ask it this way. I want from you any research that you have showing it's not addictive, and I also want any research data from you that shows it is addictive. Will you agree to submit that to us?

Mr. CAMPBELL. I see no problem supplying material. We'll get the appropriate people together from our side with the appropriate people from your side, and see how it can be handed over.

Mr. WAXMAN. Thank you.

Mr. Synar, I promised Mr. McMillan that he would be next, and that we'd let Mr. Wyden go on a little longer. So if you would permit, I'm going to go vote. We'll assume he's on his way, we'll give him another 5 minutes.

[Brief recess.]

Mr. SYNAR [presiding]. The subcommittee will come back to order. Mr. McMillan is recognized for 10 minutes.

Mr. MCMILLAN. I thank the Chair. I think that Mr. Jim Johnston in his opening statement characterized the nature of what we're here for. The real motive behind most of this is a ban on the use of tobacco and not a whole host of other things that are being asserted. On CNN last night, the gentleman from Oregon, on CNN last night, said that he was not interested in banning tobacco, but my perception is that the contrary is true and I do not think we should approach it that way.

If we're going to abide by the chairman's opening statement, then the same standards that we apply to tobacco should be applied to other products. I think that's been suggested here today in a number of ways, including a wide range of products—alcohol, caffeine content products, sugar content products, fat content products—we could go on down that list.

I think it's important to be candid in what we are talking about. I've smoked in the past. I've used alcohol in the past. Nicotine, I think, is essential to the use of tobacco. Alcohol is essential to the use of alcoholic products. I drink coffee. I don't like it if it doesn't have caffeine in it. I like candy. I don't think I'd like it if it didn't have chocolate or sugar.

The question is how do we deal with the fact that use to excess or misuse of certain products may be harmful in one way or another. They can be harmful physically. They can be harmful psychologically. They can modify behavior.

Somehow or another, in all this, we don't seem to be applying any commonly accepted standards with respect to similar products and I don't know how to deal with this issue rationally unless we do.

My first question has to do with the much ballyhooed list, the so-called secret list that became public. Why was nicotine not included on the list of 600 items that were disclosed? Anyone can answer.

Mr. JAMES JOHNSTON. Congressman, it's because nicotine is the natural component of the tobacco leaf. Nicotine sulfate was on the list. It's present because it is required to be there by the BATF. It's in minuscule quantities.

This cup, if poured into a 3,000 gallon swimming pool, would represent how much nicotine is present in that nicotine sulfate. It can't even be measured. And it's required to be there by the BATF.

Mr. MCMILLAN. We don't require a secret list of the 30 to 40-plus additives that go into a bottle of gin in excess of alcohol, do we? Over and beyond alcohol. Most of us don't even know what they are.

Mr. JAMES JOHNSTON. The ingredients released by these manufacturers yesterday goes far beyond what has ever been provided by any manufacturer of food products. They're not required to disclose processing agents. We have supplied those data to the U.S.

Government for over 10 years. We have fully cooperated with the Department of Health and Human Services.

A prior chairman of this company testified before Congress in 1964 and offered our ingredient list to Congress 30 years ago this year. We've not been trying to hide anything. We've been fully cooperative on this. We've been highly responsible in having not only each of those ingredients analyzed, but analyzed in totality, analyzed in totality by independent toxicologists.

Mr. MCMILLAN. On the subject of the chart, Mr. Campbell, that was subsequently discussed with respect to the testimony of Dr. Kessler and relative content of tar and nicotine, isn't it true over that period of time that we also went through a transition in production of cigarettes, trying to conform to consumer preference, and that probably embraces the introduction and growth of filter-tipped cigarettes and the decline of non-filter-tipped cigarettes?

How does that enter into the equation?

Mr. CAMPBELL. There's been a number of things put up to show that the overall levels of tar and nicotine over the last 40 years have dropped in the neighborhood of 60 percent. Dr. Kessler maintained that that had stopped after 1982 and that somehow the nicotine level was going up.

Well, Mr. Johnston's charts actually, once Dr. Kessler's data was available to us and they could break it down, shows that the tar and nicotine has admittedly slowed down in terms of its average consumption, but it's still going down and nicotine and tar are going down together, as they always have.

Mr. MCMILLAN. The introduction of filter-tipped cigarettes came about for what reason?

Mr. CAMPBELL. I think that the introduction of filter-tipped cigarettes was in about 1953 or 1954 and I think that what happened was that the consumers expressed that they wanted a better way to smoke and consumers were expressing an interest in, at that time, more mildness. But it has since become an interest in tar and nicotine and we've responded.

Mr. JAMES JOHNSTON. And, Mr. Congressman, there were public health concerns about tar. There were requests by the public health and scientific communities to reduce tar in cigarettes. It is quite a remarkable result that has been achieved.

Mr. MCMILLAN. The filter tip, did it not only reduce tar, but also reduce nicotine?

Mr. JAMES JOHNSTON. Yes.

Mr. MCMILLAN. Proportionately?

Mr. JAMES JOHNSTON. Its intent was to reduce tar. By reducing tar, it roughly proportionately brought nicotine down, as well. That wasn't the intent by the manufacturers. In the context of this hearing today, however, it is important because of all the allegations that have been made about nicotine.

I point to one simple thing, which is if we had this Nation of addicts—now, addicts demand increasing dosages of products, of that substance. Heroin users go from 1 shot a day to 2 to 3 to 4. Here is a Nation that has decreased its consumption of nicotine by two-thirds. Common sense says this is not some overwhelming——

Mr. MCMILLAN. But in the filter tip, there is a presumption of removing something that was perceived to be potentially damaging

and the industry responded to it and the consumer demonstrated a preference for it. Isn't that the truth or not?

Mr. JAMES JOHNSTON. Tar. Yes, sir. Tar.

Mr. MCMILLAN. Yes. And tar was the one that was identified as a problem, not nicotine.

Mr. JAMES JOHNSTON. That's correct.

Mr. MCMILLAN. Although there may be some problems with nicotine taken to excess. Has the government ever attempted to regulate the amount of nicotine that goes into a cigarette? It requires disclosure, I understand that, but has there ever been an attempt to limit it?

Mr. JAMES JOHNSTON. Not until recently, there hasn't. Smokers know, have always known that nicotine is part of the natural product. It's been in the common vernacular for a long time. What has scared smokers out of what are truly hysterical charges being made is that we are somehow adding nicotine to hook them or addict them.

One simple chart, the Surgeon General's chart shows it's been just the opposite. A two-thirds reduction. We owe it to the American people for this subcommittee, after they've done whatever work they need to do, to go on record to say it is not true. We've checked this out, we agree with the tobacco manufacturers, we agree with the Surgeon General of the United States that nicotine has been reduced, not increased.

Mr. MCMILLAN. Has it ever been the intent of the law to require that tobacco products be sold with a nicotine content less than that naturally occurring in a typical blend of tobacco products or tobacco leaf?

Mr. CAMPBELL. No, absolutely not. The nicotine has just gone down on its own in response to consumers' interest in these areas.

Mr. MCMILLAN. Has my time expired or can I continue?

Mr. WAXMAN You can take another minute.

Mr. MCMILLAN. Let me just conclude this round of questioning. I think it's been said, but it's worth repeating. Anyone answer this question. Does anyone produce a tobacco product in which you deliberately try to engineer a nicotine content in excess of the natural content of the tobacco leaf used in the product?

Mr. CAMPBELL. Absolutely not.

Mr. MCMILLAN. In fact, the opposite is true, right? You do engineer a product, the filter tip is a case in point, of product that is below the norm that would be contained in the leaf itself.

Mr. CAMPBELL. Dramatically.

Mr. MCMILLAN. That's a true statement.

Mr. JAMES JOHNSTON. Dramatically.

Mr. MCMILLAN. Thank the Chair.

Mr. WAXMAN. Thank you, Mr. McMillan. Before I recognize Mr. Synar, just for housekeeping purposes, Mr. Campbell, my staff wanted me to make this very clear for the record. What we're requesting of you is any report, memorandum or other document describing research conducted by Philip Morris on nicotine and addiction, regardless of whether the document shows nicotine is addictive or that it is not addictive.

If you need to have our staffs meet about that, we will certainly make our staff available. But we would like a commitment from you to get that.

Mr. CAMPBELL. I hear your request. I'll have to take it—I'll make the commitment to look into it and to put the two staffs together. I don't know if there are any privileged documents involved. I'm not sure.

Mr. WAXMAN. You're the Chief Executive Officer. For what reason could you not give us this research if it's been conducted?

Mr. CAMPBELL. I have no problem giving you any material we have if it's not in some way involved in active litigation at this time.

Mr. WAXMAN. Let me tell you that litigation is not a reason not to give the Congress of the United States information. We expect to get it. Mr. Synar?

Mr. SYNAR. Let me reiterate that there is absolutely no legal reason why you should not be required to provide that information. Your lawyers know that proprietary information provided to Congress does not make it public. It would be handled in a confidential manner.

Gentlemen, I'm a little bit distressed as I hear some of your answers with respect to your flippant attitude on the impact of nicotine and its addictiveness and the impact of cigarettes in general.

I call to your attention to your left, that stack of books, overwhelming medical evidence, over the last 25 years of the addictiveness, as well as the hazard of the product that you produce.

Mr. Campbell, 2 weeks ago, Congressman Waxman released a study written by Dr. Victor DeNoble. I'd ask unanimous consent to enter in the record at this time Exhibit 5-A.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SYNAR. As you know, Dr. DeNoble was a research scientist at Philip Morris during the early 1980's. You have in front of you the DeNoble study. Dr. DeNoble was studying the nicotine of rats. In 1983, he found that rats will self-administer nicotine when hooked up to an intravenous nicotine solution. In other words, they will work to get nicotine. And as Dr. Kessler told us in the hearing in which he testified, self-administration of this type is hallmark addiction.

I'd ask unanimous consent to enter in the record Exhibit 6.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SYNAR. Mr. Campbell, before you is a press release, your press release that said that Dr. DeNoble's study showed exactly the opposite. I have a copy here, which is marked, and it says that the DeNoble study showed that nicotine is "in a class of non-addictive chemical compounds, such as saccharine or water."

I don't think any of us are ever going to find, Mr. Campbell, a study that shows rats or any other animals will self-administer saccharine or water intravenously the way they do nicotine.

I ask unanimous consent to enter in the record Exhibit 7.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SYNAR. Mr. Campbell, this is a letter from the Director of the National Institute of Drug Abuse regarding the DeNoble study which is in question here. This letter directly contradicts your assertions. According to the expert Federal agency on drug abuse, and let me quote from it, "These findings from the DeNoble study indicate that nicotine has reenforcing properties, one of the hallmarks of addictive substances."

Yet, with this overwhelming evidence by medical experts, you continue to contend that your study shows the opposite. Would you have this subcommittee believe that the National Institute doesn't know how this study was conducted or understand it at all?

Mr. CAMPBELL. I can't comment. I obviously just received the document for the first time.

Mr. SYNAR. Mr. Campbell, was Dr. DeNoble's work part of your company's effort to develop a nicotine analog, which are chemicals which would have addicting or reenforcing features without any of some of the nicotine side effects? Yes or no?

Mr. CAMPBELL. Yes.

Mr. SYNAR. OK. I have here and I ask unanimous consent to enter in the record Exhibit 8.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SYNAR. It is a 1980 internal memorandum written by one of your scientists, J.L. Charles. This memorandum describes nicotine receptor research that your company was funding at the University of Rochester.

Was this related to Dr. DeNoble's work?

Mr. CAMPBELL. I studied this matter in general, but you've now entered into a depth of study that I—can I ask Dr. Ellis to help me?

Mr. SYNAR. Mr. Campbell, was this part not—turn around and ask them. Was this part of Mr. DeNoble's work?

Mr. CAMPBELL. Yes.

Mr. SYNAR. I ask unanimous consent to enter in the record Exhibit 9.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SYNAR. There's something that bothers me, Mr. Campbell, even more than your complete misrepresentation and characterization of the DeNoble work. It's the apparent attempt by your company to suppress the findings in the DeNoble study and to keep the important study secret because it might hurt the industry.

Now, let me go through the chronology with you. Dr. DeNoble submitted his study to a leading scientific journal, Psychopharmacology, in 1983. It was peer reviewed. It was accepted for publication. It was edited. Then, at the last minute, Dr. DeNoble withdrew the study.

In a letter written to Philip Morris on Philip Morris stationery, which you have before you, Dr. DeNoble explained that he was withdrawing that study "for reasons beyond my control."

Dr. DeNoble resubmitted that study in 1985, Mr. Campbell. It went through the same peer process. I'd ask for Exhibit 10 to be made part of the record.

Mr. WAXMAN. Without objection, that will be the order.

[Testimony resumes on p. 685.]

[Exhibits 5-A through 10 follow:]

DOCUMENT 4

Exhibit 10

22 September 1986

Victor J. DeNoble, Ph.D.
Ayerst Laboratories Research, Inc.
CN 8000
Princeton, NJ 08543-8000

Dear Victor:

The revised version of your MS 868-1686, received 4 August, is satisfactorily improved and abbreviated. Thanks for your thorough, effective changes.

My routine check for discrepancies between the reference list and citations in the text has revealed that Lang et al. (1977), cited on pages 3 and 11, is not in the reference list. Since it was in the reference list in the prior version, this one of the 16 reference list items deleted apparently should have been retained.

I share the distress you expressed in your phone conversation of 18 September that the Philip Morris Company has issued an injunction against publication of this paper. I am returning to you the typescript, including the glossy prints of the four figures. I will accept your paper for publication and send it to the Technical Editor only if I receive from you a corrected typescript with the information that the injunction has been lifted.

When I return to the author a manuscript that I accept will be acceptable after revision, I keep it in a pending status for six months. At the end of that time, I send to the Journal's Production Office a circulation slip specifying that the paper will not be published. I will follow this procedure unless I receive contrary instructions from you.

Although it is disappointing both for you and for me that the efforts on this paper by you, by two expert reviewers, and to a lesser extent by me will apparently not result in publication, I believe that your effort and experience will be beneficially applied to your future papers. You have my best wishes for success in your ongoing and future research, and for useful publications reporting your findings.

Sincerely yours,

Herbert Barry, III, Ph.D.
Field Editor for Behavioral Pharmacology
in laboratory animals

Encl.

Mr. SYNAR. It then had to be withdrawn again. According to this letter written to the journal editor, the reason was that Philip Morris had "issued an injunction against publication of this paper." The letter was from the editor, as you can see.

Mr. Campbell, do you deny that Philip Morris kept the DeNoble study from being published?

Mr. CAMPBELL. I will not deny that.

Mr. SYNAR. You did keep it from being published.

Mr. CAMPBELL. Yes. We did not in any way employ legal techniques, such as injunctions, but we did not choose to publish that.

Mr. SYNAR. Isn't it true, Mr. Campbell, that prior to the time that Dr. DeNoble submitted his study to the journal in 1983, his study had been reviewed by Philip Morris for publication?

Mr. CAMPBELL. I believe that to be the case, yes.

Mr. SYNAR. All right. In its press release, Mr. Campbell, Philip Morris states that it did not obtain an injunction against the publication. My question to you is did Philip Morris, its attorneys or any of its employees threaten a court injunction that would be sought against Dr. DeNoble if the article was published?

Mr. CAMPBELL. Not to my knowledge, sir, and I have investigated to some extent.

Mr. SYNAR. Do you have a written memo on that investigation from your staff?

Mr. CAMPBELL. I don't think so.

Mr. SYNAR. If you do, would you leave that memo available for the record and submit it?

Mr. CAMPBELL. Thank you.

[The following letter was received:]

Mr. SYNAR. The subcommittee was informed, Mr. Campbell, that in early 1984, Philip Morris or Berkeley closed down the research laboratory of Dr. DeNoble and his colleagues and the employees were told to find other jobs. Is that true?

Mr. CAMPBELL. That's correct.

Mr. SYNAR. Is it true that Philip Morris took that action because of the adverse research findings that were being found by the laboratory?

Mr. CAMPBELL. No.

Mr. SYNAR. Does Philip Morris have copies of any of Dr. DeNoble's studies, reports, notes or any other documents pertaining to work he performed or any other documents pertaining to his animal research?

Mr. CAMPBELL. I would think that we do, sir.

Mr. SYNAR. Will you provide those documents to the subcommittee and for the record?

Mr. CAMPBELL. I see no problem.

Mr. SYNAR. The subcommittee contacted Dr. DeNoble, Mr. Campbell, to ask his version of the events and Dr. DeNoble informed this subcommittee that he would be unable to talk to us because it may be subject to a confidentiality agreement that he has with your company, Philip Morris. Therefore, it would bar the testimony of Dr. DeNoble because of that agreement.

Mr. Campbell, will you release Dr. DeNoble from his confidentiality agreement so that he can appear voluntarily before this subcommittee to tell us what really happened?

Mr. CAMPBELL. I don't know of the confidentiality agreement. So I'd have to have an investigation, but then I will answer.

Mr. SYNAR. Will you release Dr. DeNoble from any contractual arrangements that would allow him to voluntarily testify before this subcommittee?

Mr. CAMPBELL. Dr. DeNoble is quite on record in a——

Mr. SYNAR. Yes or no? Will you allow Dr. DeNoble to come forward?

Mr. CAMPBELL. I see no problem and our people will discuss it with you.

Mr. SYNAR. No. That's not the question. Mr. Campbell, Dr. DeNoble will voluntarily appear if he can get through the agreement that he has with your company. Will you release him from that agreement?

Mr. CAMPBELL. Can I check with my counsel at this time?

Mr. SYNAR. I just want to know. You're the chairman of the board.

Mr. CAMPBELL. No, I'm not, sir. I'm just the president, but——

Mr. WAXMAN. Mr. Synar, let's give him a minute.

Mr. SYNAR. All right.

Mr. CAMPBELL. We'll do it, sure.

Mr. SYNAR. Thank you. Mr. Johnston, do you currently have animal research going on in your laboratory?

Mr. JAMES JOHNSTON. I believe we do, yes.

Mr. SYNAR. Will you make available to the subcommittee all documents pertaining to that animal research that you are presently and have in the past conducted?

Mr. JAMES JOHNSTON. Those which do not involve proprietary product development——

Mr. SYNAR. Mr. Johnston, that is an unacceptable answer. Proprietary information is available to Congress in confidential form. That is not a legitimate excuse for not providing it to the subcommittee.

Mr. JAMES JOHNSTON. Congressman, may I finish my response?

Mr. SYNAR. You may finish.

Mr. JAMES JOHNSTON. Those documents which relate to specific product development, it is my clear understanding that without being very careful with those documents, we could then have the Justice Department come after us for anti-competitive behavior. So this requires specific documents.

I have no problems with cooperating with this committee in any way.

Mr. SYNAR. Mr. Johnston, I take that as a yes that you will provide all the animal research and laboratory information that you are presently——

Mr. JAMES JOHNSTON. We will provide any reasonable data.

Mr. SYNAR. No. That's not what I'm suggesting, Mr. Johnston. That's not up to your determination what is reasonable. I'm asking you, will you and will every one of the gentlemen to your right provide all present and previously conducted animal research data to this committee that has been done, and reports, notes, et cetera. Mr. Johnston?

Mr. JAMES JOHNSTON. I will repeat if——

Mr. SYNAR. Yes or no, Mr. Johnston?

Mr. JAMES JOHNSTON. If there is a possible violation of anti-competitive law——

Mr. SYNAR. Mr. Johnston, let me give you the rules. Maybe you don't understand——

Mr. JAMES JOHNSTON. I will not knowingly——

Mr. SYNAR. Mr. Johnston.

Mr. JAMES JOHNSTON [continuing]. Violate the law.

Mr. SYNAR. Mr. Johnston, you cannot withhold information from the U.S. Congress. Now, we can either ask you to provide that information or we can use our subpoena power to do that. There is no bar from that information on the basis that it is proprietary or that there is pending litigation.

We will have our lawyers explain to your lawyers, if that's necessary and I don't think it is, that the providing of proprietary information does not constitute making that information public, therefore violating any formulas or particular private information that you have.

Now, the question I ask you one more time and to each gentlemen to your right. Will you provide us all the test reports and notes from all animal laboratory testing that you are presently or formerly been involved in? Yes or no?

Mr. JAMES JOHNSTON. I will provide those documents which do not threaten a Justice Department charge of anti-competitive behavior and I will require, Mr. Congressman, some kind of assurance from the subcommittee staff that those proprietary, competitive information be held in confidence. We've had some issues late-

ly of data being released in an inflammatory sense, in possible violation of a Federal——

Mr. WAXMAN. Just a minute. The question is whether you're going to submit this data. You're not suggesting that this subcommittee has released any data you've submitted to us in confidence in any improper way, are you?

Mr. JAMES JOHNSTON. No, Mr. Chairman.

Mr. WAXMAN. You will submit the data. May I have the answers from the others? We'll have to move on.

Mr. TADDEO. I'm unaware that we have any in-house animal research.

Mr. WAXMAN. Speak into the microphone.

Mr. TADDEO. I'm unaware that we have any in-house animal research.

Mr. WAXMAN. Whatever you have, we want you to submit it to us. Will you agree to that, Mr. Tisch?

Mr. TISCH. Yes, sir. We will provide to Congress whatever is appropriate and required by law, sir.

Mr. SYNAR. Gentlemen, let me explain to you something. If we have to subpoena this information, you will not be able to determine the appropriateness of the information. So you can either voluntarily agree to submit all information, including notes, records, et cetera, or the subcommittee may be forced to consider a subpoena, through which we will get all the information.

Mr. TISCH. I understand that, sir.

Mr. WAXMAN. Are you committing to cooperate with the subcommittee and get us the data?

Mr. TISCH. I have not, not cooperated, with the committee. Like I said, I will be glad to provide whatever is appropriate and whatever you require of us and whatever you ask of us.

Mr. WAXMAN. Mr. Horrigan?

Mr. HORRIGAN. We will cooperate. And if I may, at this juncture, I am somewhat appalled by the conduct of this hearing. You invited responsible executives here to devote their time and their honesty to the answers. You overwhelm people with questions. You ask yes and no. And I would like to think if we were going to have an exchange here, a true exchange, for you to be informed rather than have your minds made up, we should be given chances in future questioning to expand, if necessary.

Mr. WAXMAN. Mr. Horrigan——

Mr. HORRIGAN. We will cooperate fully with the question represented by Mr. Synar.

Mr. WAXMAN. So your answer is yes. Mr. Sandefur?

Mr. SANDEFUR. Yes. We will cooperate. We have not done any animal research.

Mr. WAXMAN. Mr. Johnston?

Mr. DONALD JOHNSTON. Yes. We will cooperate. We have not done any such studies in our own facilities. However, I would point out that in the period of the 1930's through the 1960's, we did participate in a program of grants with the Medical College of Virginia, and that information may be something we can provide.

Mr. WAXMAN. Thank you very much. Mr. Bryant?

Mr. BRYANT. Thank you very much. I would like to ask each of you sort of a rhetorical question I think I know the answer to already. But it is true, is it not, that in product liability cases that have been filed against the tobacco companies that seek to hold your companies responsible for the illness or death of a smoker, one of the defenses which the tobacco companies always assert is that the sick or dead individual who smoked did so as a matter of his or her own free choice and that he or she, therefore, assumed the risk of diseases which are publicly associated with smoking.

Isn't that the case, Mr. Johnston?

Mr. JAMES JOHNSTON. There is virtually universal awareness by the American public of the health risks involved in smoking. That is part of litigating these issues.

Mr. BRYANT. I just asked a question. I do not want to cut you off, because I want you to be able to give a full answer. But you have got to answer the questions pretty quickly. It is the case, is it not, that your usual defense is the smoker smoked voluntarily as a matter of free choice and, therefore, assumed the risk and you are not responsible? Is that not the case?

Mr. JAMES JOHNSTON. That's correct, sir.

Mr. BRYANT. Is it also true that your argument that smokers continue to smoke as a matter of their own free choice is a key part of the defense? It is the essential part of your defense. Is that not right?

Mr. JAMES JOHNSTON. I wouldn't characterize it as essential. It is part of the defense, yes, and part of the American record.

Mr. BRYANT. Is it not the case that that defense would be wiped out if you conceded here today or any forum that nicotine and your products are addictive?

Mr. JAMES JOHNSTON. Mr. Congressman, I don't know. Addiction is a term that is——

Mr. BRYANT. We all know what it means. Would it not be the case if you conceded here today that nicotine was addictive and your products were addictive, that you would no longer be able to claim that the sick or dead individual smoked as a matter of free choice? Is that not the case?

Mr. JAMES JOHNSTON. I can tell you what juries believe. Juries usually believe, because of the common definition of addiction, that the person was addicted, but the person can quit.

Mr. BRYANT. The fact of the matter is that you can not sit here today and say to us that people made a free choice to smoke if you also concede that once a person starts, they are addicted. Now, you cannot do that.

So it is very clear that you all have a very clear economic interest in telling the American people and in sustaining the idea and saying and not deviating from the assertion that your products are not addictive. I think that is just a matter of logic.

Mr. JAMES JOHNSTON. I respectfully disagree with you. The truth, Mr. Congressman——

Mr. BRYANT. So you think a person could be addicted to cigarettes and you could still assert that they smoked as a matter of free choice.

Mr. JAMES JOHNSTON. I'm telling you that the truth is the truth. I will speak the truth as I know it, disregarding litigation consequences. If we——